"The list of team veterinarians approved to export bovine embryos to the European Union is listed in the IRRS file EE.EM.VT."

July 1994

HEALTH CERTIFICATE FOR THE EXPORTATION OF BOVINE EMBRYOS TO THE EUROPEAN COMMUNITY (EC)

1. Consignor (name and full address)

ANIMAL HEALTH CERTIFICATE
No. _____ ORIGINAL

2. Third Country of Collection

3. Consignee (name and full address)

4. Competent Authority

NOTES

(a) A separate certificate must be issued for each consignment of embryos

(b) The original of this certificate must accompany the consignment

5. Competent Local Authority

6. Place and date of loading

7. Name and address of embryo collection team or embryo production team (1)

8. Means of transport

9. Place and Member State of destination

10. Registration number of embryo collection team or embryo production team (1)

11. Number and codemark of embryo containers

12. Identification of consignment:
Embryos (a) derived by in vitro fertilization yes/no (1)
(b) subjected to penetration of zona pellucida yes/no (1) ___
(a) Number of embryos _____ (b) Date(s) of collection _____ (c) Breed _____

13. I, the undersigned official veterinarian of the Government of
the United States certify that:
(name of exporting third country)

1. The embryo collection/production team identified above:

- is approved in accordance with Chapter 1 of Annex A to Directive 89/556/EEC.

- carried out the collection, processing, or production and storing and transport of the embryos described above in accordance with Chapter II of Annex A to Directive 89/556/EEC.

- is subjected at least twice per year to inspection by an official veterinarian;

2. According to official findings the United States has:
(name of exporting country)

(a) been free during 12 months immediately prior to collection of the embryos to be exported from rinderpest:
(b) either (1):

(i) has been free from foot-and-mouth disease during the 12 months immediately prior to the collection of the embryos to be exported and does not practice vaccination against it

or

(ii) has not been free from foot-and-mouth disease for the 12 months immediately prior to the collection of the embryos and/or practices vaccination against it and

- the donor females and the donors of ovaries, oocytes and other tissues used in the production of embryos come from a holding in which no animal has been vaccinated against foot-and-mouth disease during the 30 days prior to collection,
and
- the embryos have been stored in approved conditions for a minimum period of 30 days immediately after collection;

(c) either (1):

(i) has been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection of the embryos to be exported and does not practice vaccination against them
or
(ii) has not been free from bluetongue and epizootic haemorrhagic disease (EHD) for the 12 months immediately prior to collection of the embryos to be exported and/or practices vaccination against them and
- the embryos have been stored in approved conditions for a minimum period of 30 days immediately after collection, and

- the donor females and the donors of ovaries, oocytes or other tissues used in the production of embryos were subjected with negative results to an agar gel immuno diffusion test and a serum neutralization test for epizootic haemorrhagic disease antibodies on a blood sample taken not less than 21 days following collection;

3. (a) the premises on which the embryos to be exported or the ovaries, oocytes or other tissues used in the production of embryos to be exported were collected and processed was at the time of collection situated in the centre of an area of 20 km diameter in which according to official findings there had been no incidence of foot-and-mouth disease, bluetongue, epizootic haemorragic disease, contagious vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia for 30 days immediately prior to collection and in the case of embryos certified under 2(b)(ii) and (c)(ii) for 30 days after collection;

(b) between the time of collection or production of the embryos to be exported and their dispatch, they were stored continuously in approved premises which were situated in the center of an area of 20 km in diameter in which according to official findings there was no incidence of foot-and-mouth disease, contagious vesicular stomatitis or Rift Valley fever;

4. the donor females and the donors of ovaries, oocytes or other tissues used in production of embryos:

(a) during the 30 days immediately prior to collection of the embryos to be exported, were located in premises situated in the center of an area of 20 km in diameter in which according to official findings there was no incidence of foot-and-mouth disease, bluetongue, epizootic haemorrhagic disease, contagious vesicular stomatitis, Rift Valley fever or contagious bovine pleuropneumonia;

(b) showed no clinical sign of disease on the day of collection;

(c) have spent the 6 months immediately prior to collection in the territory of the United States (name of exporting Country) in a maximum of two herds which are:

- according to official findings free from tuberculosis,
- according to official findings free from brucellosis,
- free from enzootic bovine leukosis or a herd or herds which has/have shown no clinical signs of enzootic bovine leukosis during the previous 3 years.
- a herd or herds which has/have shown no clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis during the previous 12 months

5. the embryos to be exported were conceived as a result of artificial insemination or in vitro fertilization with semen from a donor sire standing at a semen collection centre approved by the competent authority for the collection, processing and storage of semen or with semen imported from the European Community.

Done at _____ _____

Signature(2) _____

Name and qualification (in block letters):

Stamp(2)

_____

_____

_____

(1) Delete as appropriate.

(2) The signature and the stamp must be in a colour different to that of printing.

NOTE: This certificate must:

(a) be drawn up in at least the official language of the Member State of destination and the Member State where the embryos will enter Community territory;

(b) be made out to a single consignee;

(c) accompany the embryos in the original.

*******EXPLANATORY NOTES******

(A) The EC Council Directive of September 25, 1989, states that, "For the purposes of embryo collection, donor animals must have spent the previous 6 months within Community territory or in the third country of collection (US) in at least one herd which is officially brucellosis free or brucellosis free..."

This means that in addition to originating from a Class Free State or a certified brucellosis-free herd, a donor cow may qualify as a "herd addition" to a certified brucellosis-free herd by being subjected to a blood test for brucellosis, with negative results, within 30 days before being moved. In addition, all other requirements for interstate or intrastate movement must be met. The cow must also have a blood test for brucellosis, with negative results, between 60 and 120 days after being added to the herd. The donor cow will be eligible for embryo collection after being a resident for at least 6 months in the certified brucellosis-free herd.

(B) The EC Council Directive of September 25, 1989, states that, "For the purposes of embryo collection, donor animals must have spent the previous 6 months within Community territory or in the third country of collection (US) in at least one herd which is officially tuberculosis (TB) free.

This means that in addition to originating from a TB-free State or an accredited TB-free herd, a donor cow may qualify as a "herd addition" to an accredited TB-free herd by:

(1) originating from a herd that has passed a herd test of all animals over 24 months of age within 12 months and having an individual tuberculin test with negative results conducted within 60 days following the date of entry; or

(2) passing a negative test within 60 days prior to entering the premises of the accredited herd and being kept in isolation from all members of the accredited herd until negative to a test conducted after 60 days following the date of entry.

(C) The EC Commission Decision of February 8, 1994 amends Council Directive 89/556/EEC on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species. This Decision applies to embryos collected, processed and stored after March 1, 1994. In essence, the Decision allows in vitro fertilized (IVF) embryos to be exported to the EC. The embryo production teams collecting, processing and storing these embryos must be headed by a veterinarian approved by the EC. The team will be subjected to biannual inspections by USDA veterinary medical officers authorized to inspect embryo collection teams for eventual export to the EC.

The following information has been taken from the aforementioned Decision:

--Where micro-manipulation of the embryo which involves penetration of the zona pellucida is to be carried out, this shall be done in suitable laminar-flow facilities which shall be properly cleaned and disinfected between batches.

--Furthermore, to be approved as a team for the production and processing of embryos derived by IVF and/or in vitro culture, an embryo production team must fulfill the following additional requirements:

(a) the personnel must be trained in appropriate disease control and laboratory techniques, particularly in procedures for working in sterile conditions;

(b) it must have at its disposal a permanently-sited processing laboratory which must:

(i) have adequate equipment and facilities, including a separate room for recovering oocytes from ovaries, and separate rooms or areas for processing oocytes and embryos, and storing embryos,

(ii) have laminar-flow facilities under which all oocytes, semen and embryos must be processed; however, the centrifugation of semen may be carried out outside the laminar-flow facility, as long as full hygienic precautions are taken;

(c) where oocytes and other tissues are to be collected in an abattoir, it must have at its disposal suitable equipment for the collection and transport of the ovaries and other tissues to the processing laboratory in a hygienic and safe manner.

--All media and solutions shall be sterilized by approved methods according to the recommendations of the manual of the International Embryo Transfer Society (IETS). Antibiotics may be added to the media in accordance with the IETS manual.

--Any micromanipulation which involves penetration of the zona pellucida must be carried out in the facilities approved for the purpose, and after the last wash and examination. Such micromanipulation may only be carried out on an embryo having an intact zona pellucida.

--In the case of embryos derived by IVF, the identification may be done on the basis of a batch, but must contain details of the date and place of collection of ovaries and/or oocytes. It must also be possible to identify the herd of origin of the donor animals.

--The conditions laid down in subparagraphs (a) to (o) shall apply as appropriate to the collection, processing, storage and transport of ovaries, oocytes and other tissues for use in IVF and/or in vitro culture. Furthermore, the following additional conditions shall apply:

(a) When ovaries and other tissues are to be collected at an abattoir, the abattoir should be officially approved and under the control of an official veterinarian whose responsibility is to carry out ante-and post-mortem inspection of donors;

(b) Materials and equipment coming into direct contact with ovaries and other tissues shall be sterilized before use and after sterilization, used exclusively for those purposes. Separate equipment shall be used to handle oocytes and embryos from different batches of donor animals.

(c) Ovaries and other tissues shall not be allowed to enter the processing laboratory until completion of the post-mortem inspection of the batch. If relevant disease is found in the batch of donors, or in any animals slaughtered in that abattoir on that day, all tissues from that batch must be traced and discarded;

(d) The washing and examination procedure laid down in subparagraphs (i) and (j) shall be carried out after the culture procedure has been completed;

(e) Any micromanipulation which involves penetration of the zona pellucida shall be carried out in accordance with the provisions of subparagraph (j), after the procedures laid down in subparagraph (a) have been completed;

(f) Only embryos from the same batch of donors should be stored in the same ampoule/straw.

--Annex B of the Decision is replaced by the following:

CONDITIONS APPLYING TO DONOR ANIMALS

(1) For the purposes of embryo collection, donor animals must meet the following requirements:

(a) They must have spent at least the previous six months within Community territory or in the third country of collection;

(b) They must have been present in the herd of origin for at least 30 days prior to collection;

(c) They must come from herds which are:

--officially tuberculosis free,

--officially brucellosis free or brucellosis free,

--enzootic bovine leucosis free

(in derogation from the third indent, they may come from a herd (or herds) which is/are not leucosis-free, but for which certification has been obtained that there has not been any clinical case of enzootic bovine leukosis during the past three years;

(d) During the previous year, they must not have been present in a herd (or herds) which have shown any clinical sign of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis.

(2) On the day of embryo collection, the donor cow:

(a) shall be kept in a holding which is not subject to veterinary prohibition or quarantine measures;

(b) shall show no clinical signs of disease.

(3) Furthermore, the above conditions shall apply to live animals intended as donors of oocytes by ovum pickup or ovariectomy.

(4) In the case of donors of ovaries and other tissues to be collected after slaughter in an abattoir, they should not have been designated for slaughter as part of a national disease eradication program, nor should they have come from a holding subject to restrictions because of animal disease.

(5) The abattoir where the ovaries and other tissues are collected must not be situated in a zone subject to prohibition or quarantine measures.

The Embryo Decision was amended so that embryos produced after May 28, 1994 with semen

from bulls resident in Certified Semen Services (CSS)- approved centers are eligible for export to the EU. Embryos produced prior to
May 28, 1994 are eligible for export to the EU only if the donor cows from which they were collected were inseminated with EU- qualified semen.